IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**Kim Hansen et al.**
Application No.	**:**	**10/531,359**
Filed	**:**	**April 13, 2005**
For :		**INTERACTIVE AUTOMATIC EXTERNAL DEFIBRILLATOR PROVIDING ATTACHMENT GUIDANCE TO OPERATOR**

APPEAL BRIEF

On Appeal from Group Art Unit 3762
Examiner Michael William Kahelin

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded April 13, 2005 at reel 017361, frame 0108.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-12, and Claims 13-28 were added during prosecution. At the time of the final Office action, Claims 1-19 were canceled and Claims 20-28 were finally rejected. The claims on appeal are Claims 23-28.

IV. STATUS OF AMENDMENTS

No amendments or other filings were submitted in response to the final rejection mailed August 6, 2009. A notice of appeal was timely filed on October 20, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention is a method for guiding an operator of an automatic external defibrillator (AED) in pad placement on a subject. Most people have seen a scene in a movie or TV show in which a patient is lying in a prone position and a doctor presses the paddles of a defibrillator against the patient's chest and yells "Clear!", after which a shock is delivered by the paddles to defibrillate the patient's heart. Before the doctor yells "Clear!" in real life, the defibrillator must be carefully set up by the doctor, as the defibrillator in these scenes is a hospital defibrillator (also called an ALS or advanced life support defibrillator or a crash cart defibrillator). Hospital defibrillators are operated only by medical personnel skilled in their use. The physician must first attach ECG electrodes to the patient and read the patient's heart rhythm to determine from the ECG whether the heart rhythm indicates that electrotherapy is appropriate for the patient's condition. If the physician makes an affirmative diagnosis, the defibrillator settings are then adjusted for parameters such as the desired energy level, the type of shock pulse to deliver, number of shocks, and so forth. Only after the physician has made the diagnosis to apply a shock and the hospital defibrillator is set up appropriately can the shock be delivered.

The subject of this invention is not hospital defibrillators, but AEDs. AEDs are designed to be used by people with little or no defibrillator or even medical training, referred to as "first responders." Since a victim of cardiac arrest must be resuscitated within twelve minutes before permanent disability or death occurs, AEDs are designed to instruct first responders in their use on the spot with voice prompting, and to make the appropriate diagnosis of the heart rhythm. It is for these reasons that AEDs have become ubiquitous in airports, shopping malls, and other public buildings.

Unlike hospital defibrillators, AEDs do not use paddles, they use flexible, adhesively attached electrode pads to sense the patient ECG signal and deliver the shock. These pads resemble large ECG electrodes of the type which are used to take a person's cardiogram. Virtually all untrained first responders have never seen or used such pads before. The challenge for the AED, and hence the AED designer, is to produce voice prompts which guide the first responder through the preparation and attachment of the electrodes to the victim, which must be done under the intense stress of an unconscious victim who is minutes away from dying.

In an ideal world, the AED would have eyes and ears to follow the actions of the first responder. When the first responder would do something wrong, the AED would see the mistake and say, "No, do this

next, and do it this way, …" with appropriate corrective guidance, and would answer the first responder's spoken questions. Unfortunately technology has not advanced to this state, and all that an AED can do is sense a certain set of electrical changes of the electrode pads. The Brewer et al. patent, discussed more fully below, shows the conventional way to do this. The electrode pads of Brewer et al. are pre-connected to the AED while the AED is stored for use. A conductive strip electrically connects the two pads together in their storage envelope and is located in line with the tear strip of the envelope. When the envelope is torn open the conductive strip is broken and the pad impedance seen by the AED goes from about 10 ohms to several hundred ohms. The pads are stuck together in the envelope and when the rescuer separates them, the impedance goes to 10,000 ohms. The rescuer is then instructed to "please place electrodes on the patient."

Here, now, is the crux of the problem. The rescuer must now properly attach the electrodes to the patient, something the rescuer may never have done before. When done properly, the AED will begin receiving the patient's ECG signal and knows that the electrodes have been properly attached to the patient. But what if time passes and no ECG signal is received? Here is where the prior art technique breaks down. There are a myriad of reasons why the AED is not seeing the

patient's ECG signal. The electrodes may have been attached to incorrect locations on the body. The rescuer may not have pressed the electrodes into full contact with the patient's skin. Chest hair may be preventing solid adhesive contact with the skin. The electrodes may be touching each other. The rescuer may not have removed the release liner from one or both electrodes, a strip which covers and protects the adhesive hydrogel prior to use. The electrodes may be in contact with the patient's clothing. Or the plug at the end of the electrode wires may have come loose or completely disconnected from the AED. The AED is unaware of which, if any, of these problems has occurred. Faced with this dilemma, the Brewer et al. AED and other AEDs of the prior art do the only thing they can do: they issue a prompt to "please check electrodes." For an untrained rescuer in the heat of a rescue next to an unconscious victim, what does this mean? The most common response is to recall the last prompt and check if the electrodes are properly placed on the patient near the right sternum and the lower left ribcage. When the rescuer sees that the electrodes are in these locations, then what? Both the rescuer and the AED are at a loss, and in a critical, life-threatening situation.

The present inventors have gone beyond this conventional approach of the prior art to electrode prompting and have studied the problems that can occur, how they occur, and their likelihood of occurrence. From this

careful research of many case studies, they have discerned the situations that are most likely to occur and have developed an AED which, when electrodes are not attached as expected, gives corrective voice prompts. A most common occurrence with layperson rescuers is to fail to remove the release liners over the adhesive electrode pad hydrogel. People unfamiliar with AED electrodes generally do not even notice the presence of this release liner. The AED of the present invention thus issues a prompt which instructs the rescuer to remove the pad release liners if successful pad attachment has not occurred. Another common problem the present inventors have discerned is that the electrode pads are often attached to the body too close together and are touching each other. An AED of the present invention addresses this problem by issuing a correction prompt that the pads must not be touching each other. Another common occurrence which an AED of the present invention addresses is the problem of contact between the electrode pads and the patient's clothing. An AED of the present invention will issue a correction prompt which instructs the rescuer that the pads must not touch clothing. By researching these conditions and their likelihood of occurrence, the present inventors have gone beyond the teachings of the prior art and developed an AED that provides critical corrective guidance at the most critical part of the rescue for the first responder.

The independent Claims 23, 24, and 25 are supported by the drawings and specification as seen by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

23. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action; {#16a; pg. 3, ln 1-7}

sensing whether the pads are in proper contact with the subject {#13, #18; pg. 4, ln 10-11} and, if they are not;

following sensing, issuing a pad correction prompt to remove a pad liner. {#16b; pg. 4, ln 23-25}

24. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action; {#16a; pg. 3, ln 1-7}

sensing whether the pads are in proper contact with the subject {#13, #18; pg. 4, ln 10-11} and, if they are not;

following sensing, issuing a pad correction prompt that the pads must not be touching each other. {#16b; pg. 5, ln 11-13}

25. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action; {#16a; pg. 3, ln 1-7}

sensing whether the pads are in proper contact with the subject {#13, #18; pg. 4, ln 10-11} and, if they are not;

following sensing, issuing a pad correction prompt that the pads must not touch clothing. {#16b; pg. 4, ln 23-26 & pg. 5, ln 11-13}

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 23 and 24 were correctly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,700,281 (Brewer et al.)

B. Whether Claims 25-28 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Brewer et al.

VII. ARGUMENT

A. Whether Claims 23 and 24 were correctly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,700,281 (Brewer et al.)

As mentioned above, Brewer et al. describe an AED with electrodes 50 which are pre-connected to the AED while the AED is stored for use as shown in Fig. 1 of the patent. A conductive strip 64 electrically connects the two electrodes together in their storage envelope 60 and is located in line with the tear line 69 of the envelope. When the envelope is torn open the conductive strip is broken and the pad impedance seen by the AED goes from about 10 ohms to several hundred

ohms. Brewer et al. suggest one embodiment in which the release liners 61 which cover the conductive adhesive 54 of each electrode are perforated (col. 4, lines 16-18). When perforated release liners are used the conductive adhesive is accessible through the perforations and, when the two release liners are pressed into contact with each other, the electrodes will stick together by the contacting conductive adhesive through the perforations. When the electrodes are stuck together in this manner they will present an impedance of several hundred ohms to the AED. When the rescuer separates the stuck-together electrodes, the impedance goes to 10,000 ohms. The rescuer is then instructed to "please place electrodes on the patient."

In the final rejection, the Examiner cites the instruction to separate the stuck-together electrodes (col. 8, lines 59-60) as a pad correction prompt to remove a pad liner. It is not. First, this prompt is issued in the normal sequence of prompting when no problem has arisen. When the prompt is given in this part of the prompting sequence of Brewer et al., there is no problem with the electrode pads that requires correcting. It is issued in the normal sequence when the preceding instructions have been correctly followed. Second, the prompt is not instructing removal of a release liner, it is instructing the rescuer to separate the electrodes by

pulling them apart. After this is done, the two release liners 61 remain on the electrode pads and have yet to be removed. When the impedance jumps to 10,000 ohms, the AED knows that the instruction to separate the electrodes has been followed. Here is where the Brewer et al. operating sequence breaks down, for there is no way for the Brewer et al. AED to know if the release liners 61 are then removed. Furthermore, there is no instruction to remove the liners, nor to know if such an instruction was successfully carried out. All that the AED knows next is that an ECG signal is received and all is well, or that no or a bad ECG signal is received and something has gone wrong. But what? Brewer et al. offer that the electrodes may not be solidly contacted to the patient (col. 8, lines 64-67), in which case the general "please check electrodes" prompt is issued. There is no pad correction prompt to remove a pad liner when pads are not sensed as being in proper contact with the patient, as recited in Claim 23. Accordingly it is respectfully submitted that Claim 23 cannot be anticipated by Brewer et al.

Claim 24 recites that, if the electrode pads are not sensed as being in proper contact with the patient, a pad correction prompt is issued instructing the rescuer that the electrode pads must not be touching each other. In paragraph 7 of the final rejection the Examiner takes the

instruction to "please pull electrodes apart" as this pad correction prompt because the pads are touching each other before they are pulled apart. Once again, this prompt by the Brewer et al. AED is not a correction prompt, as there is no problem to correct at the time it is issued. It is issued in every prompting sequence of the Brewer et al. AED, including all perfectly correct rescues. Secondly, Claim 24 requires that the correction prompt instructing that the pads must not touch each other is issued after sensing proper pad contact with the patient. As seen in col. 8, lines 58-67, Brewer et al. issue the prompt to pull the electrodes apart before prompting the rescuer to "please place electrodes on patient." Sensing for proper pad contact is not done until after the pads have been placed (or instructed to be placed) on the patient. When the pads are pulled apart, Brewer et al. expect to see simply a 10,000 ohm pad impedance. Thus, even if the Brewer et al. prompt to pull the electrodes apart were a pad correction prompt, which it is not, it still is not issued following sensing as required by Claim 24. Accordingly it is respectfully submitted that Brewer et al. cannot anticipate Claim 24.

B. Whether Claims 25-28 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Brewer et al.

Claim 25 recites that, if the electrode pads are not sensed as being in proper contact with the patient, a pad correction prompt is issued

instructing the rescuer that the electrode pads must not touch clothing. The Examiner admits in paragraph 8 of the final rejection that Brewer et al. is silent as to this prompt. Nevertheless, the Examiner maintains in the rejection that it is well known in the defibrillator art to provide a pad correction prompt that the pads must not touch clothing. In paragraph 8 of the final rejection the Examiner supports this assertion by referring the international patent publication WO 01/56652 (Freeman), with specific reference to elements 122f-h of the defibrillator operating sequence of Fig. 7B, which is described on page 14, lines 18-21 of Freeman. It is seen that this reference is to the prompt in box 122g that states "Open the person's shirt or blouse and attach the adhesive pads as shown in the diagram." First, this is not a prompt that pads must not touch clothing, it is an instruction to bare the patient's torso so the pads can be attached to the bare chest. Second, this is not a correction prompt, but a normal prompt which is issued in every sequence, whether pads are applied correctly or not. Like Brewer et al., Freeman does not envision correction prompts, which are neither shown nor suggested by Brewer et al. or Freeman. Third, the prompt of 122g of Freeman does not follow sensing for proper pad contact as required by Claim 25. In Freeman, sensing begins with the succeeding step 122h, where the AED measures the electrode impedance for the appropriate range. As stated in col. 8,

lines 11-14 of Brewer et al., the chest impedance should be in the range of 20-200 ohms when electrodes are properly positioned on a patient. For all of these reasons it is respectfully submitted that Claim 25 is patentable over Brewer et al.

Claims 26-28 depend from Claims 23-25, respectively, and it is respectfully submitted that Claims 26-28 are patentable over Brewer et al. by reason of this dependency.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 23 and 24 are not anticipated by Brewer et al. and that Claims 25-28 are patentable over Brewer et al. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of Claims 23-28 of this application which were stated in the August 6, 2009 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 23-28 are the claims involved in this appeal.

23. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action;

sensing whether the pads are in proper contact with the subject and, if they are not;

following sensing, issuing a pad correction prompt to remove a pad liner.

24. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action;

sensing whether the pads are in proper contact with the subject and, if they are not;

following sensing, issuing a pad correction prompt that the pads must not be touching each other.

25. A method for guiding an operator of an automatic external defibrillator in pad placement on a subject comprising:

prompting an operator to conduct a pad placement action;

sensing whether the pads are in proper contact with the subject and, if they are not;

following sensing, issuing a pad correction prompt that the pads must not touch clothing.

26. The method according to claim 23, further comprising repeating a prompt until the defibrillator senses that the operator has conducted the prompted action.

27. The method according to claim 24, further comprising repeating a prompt until the defibrillator senses that the operator has conducted the prompted action.

28. The method according to claim 25, further comprising repeating a prompt until the defibrillator senses that the operator has conducted the prompted action.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.